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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,862

04/30/2007

Suresh Pareek

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12/16/2008

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.

P.O. BOX 2902

MINNEAPOLIS, MN 55402-0902

EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

12/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,862	<b>Applicant(s)</b> PAREEK ET AL.	
	<b>Examiner</b> S. Tran	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

Claims 1, 4-11 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Foukes et al. US 5,498,783.

Foukes teaches a powder coating composition comprising methacrylate copolymer, plasticizer, detackifier, opacifier and pigment (abstract, columns 3-8, and examples). Opacifier is in an amount between 0-35%, comprises titanium dioxide (column 7, lines 16-34).

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehra et al. US 5,733,575.

Mehra teaches an enteric coating composition comprising methacrylate copolymer, plasticizer, detackifier, opacifier and pigment (abstract, columns 2-4, and examples). Detackifier is talc in an amount of about 5-15% (column 3, lines 28-30). Plasticizer includes polyethylene glycol having MW ranges from 1500-8000 (column 4, lines 8-18). Pigment includes titanium dioxide (column 4, lines 53-62).

It is noted that Mehra teaches the present of an alkalizing agent. However, the examiner is unable to determine the detrimental effect of alkalizing agent. Therefore, the burden is shifted to applicant to show that the present of alkalizing agent will detrimentally affect the desirability of obtaining a useful enteric coating composition. This is because Mehra teaches the desirability of providing a non-toxic edible enteric film coating dry powder composition for use in making an aqueous enteric coating

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suspension that may be used in coating pharmaceuticals, which is less tacky than known aqueous enteric film coatings in the art.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lech et al. US 5,641,513.

Lech teaches a tablet coated method comprising coating a tablet with a coating composition containing methacrylate copolymer, plasticizer, detackifier, opacifier and pigment (abstract, column 4, lines 26-49, and examples). Plasticizer includes polyethylene glycol in an amount of about 1%-40% (column 4, lines 51-63). Opacifier and pigment includes titanium dioxide and colorant (column 5, lines 1-18).

### ***Response to Arguments***

Applicant's arguments filed 09/11/08 have been fully considered but they are not persuasive.

Applicant argues that all of the cited references, Foukes, Mehra, and Lech, fail to teach methacrylate copolymer of Type C.

However, in response to applicant's arguments, it is noted that Foukes, Mehra, and Lech teach the use of methacrylic acid copolymer, generically. However, Foukes, Mehra, and Lech do not specifically point out that the generic methacrylic acid copolymer in the coating composition has to be of Type A, B or C. As such, absent of evidence to the contrary, the burden is shifted to applicant to show that the methacrylic acid copolymer taught by the cited prior arts cannot be a type C copolymer. It is noted

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that Foukes, Mehra, and Lech, teach the use of methacrylic acid copolymer for the same purpose desired by the applicant, namely, a coating composition useful in pharmaceutical art.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/  
Primary Examiner, Art Unit 1615